K002500

OCT 23 2000

510(K) SUMMARY FOR THE PRONOSCO X-POSURE SYSTEM™

VERSION 2 RAD

Submitter's Name, Address, Telephone Number, And Contact Person

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Date Prepared

August 14, 2000

Name of the Device

The Pronosco X-posure System™ Version 2 RAD

Common or Usual Name

Bone Densitometer

Classification Name

Bone Densitometer (21 C.F.R. § 892.1170)

Predicate Devices

1. Pronosco X-posure System™ Version 1 (K984178)
2. Lunar Expert-XL Forearm & Hand Acquisition/ Analysis Software (K964263, K983269) ("Lunar Expert-XL")
3. Alara MetriScan Bone Density System (K000162) ("Alara Metriscan")

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Intended Use

The Pronosco X-posure System™ Version 2 RAD is intended for use to estimate bone mineral density ("BMD") in the forearm and to assess increased risk of osteoporotic fractures according to World Health Organization ("WHO") criteria. 1/ The device is specifically indicated for use to: (1) assist the physician in diagnosing subjects who have already been identified to be at risk of suffering from osteoporosis, together with other known risk factors (*i.e.*, prior history of fractures, advanced age, low body weight, lack of physical exercise, lack of exposure to sunlight, insufficient dietary intake of calcium and vitamin D, and smoking); and (2) compare the BMD estimate with a reference population comprised of young normals and age matched normals to compute T-scores and Z-scores, respectively.

Principles of Operation

To use the system, a radiograph must first be taken of the hand and forearm using standard x-ray equipment according to the company's imaging specifications. The image is then scanned into the X-posure System™, and the software algorithm derives the BMD estimate based on analysis of cortical thickness in the second through fourth metacarpals.

1/ In general, the WHO criteria imply that subjects with T-scores (as defined *infra*) from +1 to -1 are considered normal. Subjects with T-scores from -1 to -2.5 are considered to have low bone mass (osteopenia) and an increased risk of fracture. Subjects with T-scores below -2.5 are considered to be osteoporotic and to have a high risk of fracture. World Health Organization, Assessment of Fracture Risk and its Application to Screening for Postmenopausal Osteoporosis: Report of a WHO Study Group (1994).

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Technical Characteristics

The Pronosco X-posure System™ Version 2 RAD and the predicate devices possess similar technical characteristics. The method of deriving the BMD estimate (digital x-ray radiogrammetry) is identical to the previously cleared version of the X-Posure System™. The only significant difference in technological characteristics is the modification of the regions of interest to include only the second through fourth metacarpals. However, other predicate devices, such as the Lunar Expert-XL and the Alara Metriscan also provide BMD estimates based solely on ROIs in the hand.

Summary Basis for the Finding of Substantial Equivalence

The Pronosco X-posure System™ Version 2 RAD is substantially equivalent to the previously cleared version of the device (K984178), as well as to other currently marketed bone densitometers, such as the Lunar Expert-XL and the Alara Metriscan. The intended use of the modified Pronosco X-posure System™ is identical to the previously cleared version of the device, and the technological characteristics are also substantially the same. The minor differences in technical characteristics between the modified Pronosco X-posure System™ and the predicates resulting from changes in the ROIs used to estimate BMD do not raise any new questions of safety or effectiveness, as confirmed by *in vitro* performance testing as well as clinical testing. Therefore, the devices are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 23 2000

Pronosco™ A/S
C/o Jonathan Kahan
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555 Thirteenth Street, N.W.
Washington, DC 20004-1109

Re: K002500
Pronosco X-Posure System™ Version 2 RAD
Dated: August 14, 2000
Received: August 14, 2000
Regulatory class: II
21 CFR 892.1170/Procode: 90 KGI

Dear Mr. Kahan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K002500

Device Name: Pronosco X-posure System™ Version 2 RAD

Indications For Use:

The Pronosco X-posure System™ Version 2 RAD is intended for use to estimate BMD in the forearm and to assess increased risk of osteoporotic fractures according to World Health Organization ("WHO") criteria. The device is specifically indicated for use to: (1) assist the physician in diagnosing subjects who have already been identified to be at risk of suffering from osteoporosis, together with other known risk factors (*i.e.*, prior history of fractures, advanced age, low body weight, lack of physical exercise, lack of exposure to sunlight, insufficient dietary intake of calcium and vitamin D, and smoking); (2) compare the BMD estimate with reference populations of young normals and age matched normals to compute T-scores and Z-scores, respectively.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002500